A Thesis Entitled

Common nutrition deficiency and changes in biochemical parameters in patients after bariatric surgery which may affect oral health.

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by

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INTRODUCTION:

Overweight and obesity have been recently prevalent across the globe, owing to almost a twofold increase in the past 3 decades. According to data from 2014, the global population of adults aged 18 years and older who were classified as overweight exceeded 1.9 billion individuals. Among these figures, the number of obese adults exceeds 600 million. In general, approximately 13% of the global adult populace (11% males and 15% females) exhibited obesity. A study revealed that 39% of individuals who were 18 years old and above had signs of being overweight. Further analysis indicated that 38% of males and 40% of women fell into this category. The worldwide prevalence of obesity more than doubled between 1980 and 2014 (WHO, 2021) [1]. Apart from the malnutrition battle, India has developed another nutritional problem—obesity. In the past 10 years, the number of obese people has doubled in India (NFHS-4, 2016) [2]. According to the NFHS-5, several states and union territories, including Maharashtra, Gujarat, Mizoram, Tripura, Lakshadweep, Jammu and Kashmir, Uttar Pradesh, Delhi, West Bengal, Andhra Pradesh, and Ladakh, have registered an increase in the percentage of obesity among children below five years of age in comparison to NFHS-4 conducted between 2015 and 2016 [3].

Overweight and obesity are explained as excessive fat accumulation in humans that may impair their metabolism and health (WHO, 2021). The pathophysiology of obesity is complex, and its etiology is mufti-factorial, involving genetic, behavioral and psychological factors. Factors such as dietary intake and physical activity may significantly influence its occurrence. Obesity is mainly classified by the body mass index (BMI). Therapeutic strategies to treat obesity are limited. Therefore, Bariatric Surgery (BS) is recommended for patients with a BMI above 37 kg/m2 or above 32 kg/m2 when associated with obesity-related diseases (Asian Pacific Bariatric Surgery Group (APBSG,2005) and Central Government Health Scheme (CGHS, 2013) [4].

Laparoscopic surgery is among the various invasive techniques used nowadays to perform various bariatric procedures and other revision bariatric procedures. Laparoscopy based bariatric surgery has become widely used because of

advancements in laparoscopic instrumentation and training that has resulted in improved surgical outcomes, reduced pain, faster recovery and fewer scars.

BS basically works on restricting the quantity of food and causing the minimal absorption of nutrients, leading to subsequent weight loss. The procedures can be categorized into restrictive, mal-absorptive & combination of restrictive & mal-absorptive procedures.

Restrictive procedures:

- ✓ Adjustable gastric banding (AGB)
- ✓ Laparoscopic Sleeve gastrectomy (LSG)

Mal-absorptive procedures:

- ✓ Bilio-pancreatic diversion (BPD) +/- DS (Duodenal Switch)

Combined procedures:

- ✓ Roux-en-Y gastric bypass (RYGB)
- ✓ Bilio-pancreatic diversion (BPD)
- ✓ Mini Gastric Bypass (MGB) or One Anastomosis Gastric Bypass surgery (OAGB)

Of the various procedures indicated LSG, RYGB and MGB are the most commonly performed procedures in India (Kular et al, 2014) . Here, my study intends to include the MGB procedure and its effect on "biochemical parameters " of the operating patients.

STATEMENT OF PROBLEM

Overweight and obesity are defined as abnormal or excessive fat accumulation that may impair health. Therefore, Bariatric Surgery basically works on restricting the quantity of food and causes a reduced absorption of nutrients, leading to subsequent weight loss and its maintenance over a period of time.

CLINICAL IMPLICATION OF THE STUDY

As the gastrointestinal (GI) anatomy changes post bariatric surgery, causing an alteration in the quantity of food intake and also in the absorption of macro and micro nutrients. Therefore, this combination of restriction along with mal-

absorption leads to weight loss along with metabolic corrections in individuals opting for the procedure.

AIM

The aim of this research is to address the lack of Indian longitudinal studies that have provided comprehensive information on the nutritional concerns before and after bariatric surgery, as well as the resulting impact on patients' quality of life. The current study aims to identify the prevailing changes in patients following bariatric surgery by analyzing their biochemical parameters.

OBJECTIVE

This study objective is to evaluate the prevalence of common biochemical parameters, changes in these parameters, and the resolution of co-morbidities following Mini Gastric Bypass surgery.

The particular objectives of this study are as follows: The approaches have been outlined in three distinct steps, providing comprehensive details.

PHASE 1: To evaluate alterations in blood parameters among patients who choose Mini Gastric Bypass (MGB) as a treatment option.

Phase 2 : To evaluate the impact of surgery on the quality of life (QOL) of the patients after a period of 6 months.

Phase 3 of the study involves the development of a nutrition education material that is tailored to the needs of postoperative patients undergoing medical nutrition therapy. The objective of this phase is to create a user-friendly resource that effectively communicates essential nutritional information to patients.

HYPOTHESIS

Proposed Hypothesis

Nutritional issues are seen in patients after bariatric surgery that impacts their quality of life.

Null Hypothesis

There is no noticeable disparity in nutritional concerns prior to and following bariatric surgery, and this surgical intervention significantly influences the patients' overall quality of life.

REVIEW OF LITERATURE

Rutledge R, Kular K, Manchanda N (2019)[5]: The Laparoscopic Mini-Gastric Bypass is now a routine procedure across the globe due to its acceptability by both the surgeons and the patients and in India, MGB is the 2nd commonest procedure following the sleeve Gastrectomy, outpacing the standard Roux-en-Y Gastric Bypass [RYGB].

Coskun, M. Hasbahceci, S. Bozkurt (2014)[6] The MGB method effectively targets and mitigates several perceived constraints associated with alternative surgical interventions, while also including numerous attributes that align with the characteristics of an optimal bariatric surgery. It has now been shown in many short- and long-term studies, as well as in many controlled prospective randomized trials, to result in excellent weight loss, good resolution of associated medical illnesses and very high levels of patient satisfaction.

Velotti N, Vitiello A, Berardi G, Di Lauro K, Musella M (2021)[7] MGB was first developed by Dr. Robert Rutledge in 1997. In this procedure, a long narrow tube of the stomach approximate size of 200cc along with its lesser curvature is created. A segment of the small intestine is elevated and connected to the tube at a distance of around 150-200 cm. The MGB operation has been proposed as a viable alternative to the Roux en-Y Gastric Bypass technique, mostly due to its straightforward design. This approach is gaining popularity due to its low incidence of problems and its ability to facilitate sustained weight loss. It has been estimated that 15.4% of weight loss surgery in Asia is now performed via the MGB technique.

Remedios et al (2016)[8] There exists a significant correlation between obesity and many metabolic illnesses, such as diabetes, hypertension, dyslipidemia, cardiovascular disease, and Obstructive sleep apnea syndrome (OSAS). Patients undergoing bariatric procedures have significantly experienced resolution or improvement of co- morbidities. Bowel syndrome (BS) has many effects on the nutritional status of patients, including reduced food intake, food intolerance, food aversions, desires, and impaired absorption of essential nutrients such as vitamins and minerals. In a study on 2704 individuals with a BMI of > 30 kg/m2, 43% suffered from pre-existing iron deficiency, 56.7% from vitamin B12 deficiency, 11% from

calcium deficiency, 35% from vitamin D3 deficiency and 10% from protein deficiency.

Attaluri P, Castillo A, Edriss H, Nugent K. (2018)[9] Several factors contribute to the development of vitamin B12 deficiency, including diminished hydrochloric acid production, stomach churning, reduced levels of pepsin, and inadequate intrinsic factor (IF) secretion. Both partial and total gastrectomy are recognized as significant factors contributing to the risk of vitamin B12 insufficiency. It has been observed that around one-third of individuals who have undergone these surgical procedures experience B12 deficiency within one year after bariatric surgery. Thiamin (vitamin B1) deficiency in the early postoperative months has been reported in few studies, mainly after an episode of intractable vomiting

Lombardo M, Franchi A, Biolcati Rinaldi R (2021)[10] Iron deficiency (F 64.3% vs. M 30%), vitamin D deficiency (F 38.1% vs. M 60%) and calcium (F 33.3% vs. M 0%) is also common after mal-absorptive procedure was reported in a recent study.

Brolin et al (2002)[11] The contribution of the stomach to protein digestion is rather limited, as the majority of this process takes place in the small intestine, where digestion and absorption predominantly occur. Protein malnutrition (PM) is usually associated with other contemporaneous circumstances that lead to decreased dietary intake, including anorexia, prolonged vomiting, diarrhea, food intolerance, depression, fear of weight regains, alcohol/drug abuse, socioeconomic status, or other surgical reasons like poor absorption

METHODOLOGY

Participants individuals will be recruited from the hospital and will be observed for a total duration of 12 months. This period will consist of a 6-month enrollment phase, during which subjects will be selected, and an additional 6-month follow-up phase. Specifically, participants will be assessed at 3 months and 6 months after undergoing bariatric surgery.

DATA COLLECTION

The data will be collected strictly as per the stated inclusion and exclusion criteria set for the study.

INCLUSION CRITERIA

- Patients aged 20 years and above, mixed subjects of both genders (male & female) residing in Gujarat.
- The patient agrees to participate in the study by submitting a written informed consent,
- Patients with a BMI greater than equal to 32 with or without co-morbidities.

EXCLUSION CRITERIA

- Patients who don't agree to come for follow ups
- The study will exclude subjects with any eating disorders
- To check the participants' anxiety and psychological stress, the State Trait Anxiety Inventory (STAI) and the PSS questionnaire (Sheldon Cohen) will be given to chosen subjects.
- Patients not lying in the age range or they have undergone any other bariatric procedures apart from the stated ones
- Patients currently participating in any other clinical trial
- Patients who did not give consent for the study
- NRI as their food pattern differs from the actual Indian scenario
- Physically challenged patients as data variations can be observed due to sedentary lifestyle

Weight History:

In accordance with the American Society for Metabolic and Bariatric Surgery (ASMBS) standards from 2016, the patient underwent pre-operative weight loss as recommended by the program.

Medical history:

- Previous instances of co-morbidities.
- The present pharmaceutical substances being administered.
- The topic of discussion is nutritional supplements, specifically those that encompass vitamins, minerals, and botanical components.
- Food allergies and intolerance.

Anthropometrics:

Anthropometry refers to the scientific study of human body measurements and proportions. It encompasses several parameters such as weight, height, and various body compositions. These measurements are crucial in understanding the physical characteristics and dimensions of individuals, providing valuable insights on their overall health.

Dietary Assessment:

The overall diet intake was assessed using a 24-hour recall method, which was administered separately for both weekdays and weekends. The food, mood, and activity record serves as a beneficial instrument in identifying probable omissions within food groups or dietary patterns that could potentially increase the likelihood of nutritional deficiencies.

Biochemical Parameters:

Various blood parameters were analyzed at 0 month, 3 months and at 6 months post surgery. Important parameters like complete blood count (CBC), Liver Function Test (LFT), Renal Function test (LFT), Lipid profile, Thyroid Function Test (TFT), and other vitamin assays like serum vitamin B12, vitamin D3, ascorbic acid, ionic calcium and iron levels were done. Other topics under consideration was the quality of life (QOL) following bariatric surgery.

Furthermore, an educational material on Nutrition and Health was formulated for educating the patients.

DATA ANALYSIS & MONITORING:

- The daily records and surveys will undergo a process of cross-checking to identify any missing data and, afterward, ensure that they are updated.
- All the biochemical parameter data will be taken on 0-months, 3-months, and 6-months for the subject.
- All data will be entered in MS excel and transported to SPSS software for statistical analysis.

The 1st step in statistical analysis involves descriptive analysis of the data

gathered. All the data will be suitably sorted, coded and then put into an MS excel spreadsheet and then will be treated for further statistical analysis using SPSS (Statistical Package for the Social Sciences) software (version 23).

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